

Notice of Allowability

Application No.

09/493,211

Examiner

Chih-Min Kam

Applicant(s)

APPELMELK ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/24/03.
2. ☒ The allowed claim(s) is/are 1,3-13,15-23,26-30,40 and 42-50.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No. 12.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>25</u> |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

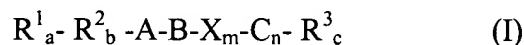
Authorization for this examiner's amendment was given in a telephone interview with Drew Hissong on April 24, 2003.

Examiner's Amendments to the Claims:

Please cancel claims ~~14~~ and ~~31-39~~.

Claims 1, 5, 8-12, 15, 22, 28 and 44-48 have been amended as follows:

1. (Thrice amended) An isolated peptide comprising at least 12 amino acids, [the peptide having an amino acid composition such that] wherein the peptide is amphipathic, cationic and forms a stable α -helix, and is represented by the following formula (I) or the retro orientation of formula (I):



wherein

R^1 , R^2 , and R^3 are each an amino acid, and a, b and c are each independently an integer from 0 to 15, wherein each R^1 for each value of a [(which is an integer from 0 to 15)], each R^2 for each value of b [(which is an integer from 0 to 15) and] and each R^3 for each value of c [(which is an integer from 0 to 15), each R^1 , R^2 , and R^3 is] are independently the same or different [for each R^1_a , R^2_b , and R^3_c],

wherein the combination of $a+b$ is not greater than 15,

each A is an amino acid independently selected from the group consisting of Lys, Arg, and His,

each B is an amino acid independently selected from the group consisting of Phe, Trp, and Tyr,

each C is an amino acid independently selected from the group consisting of Leu, Ile, Val and Ala,

X [may be] is (A-B-C-A) or (A-C-B-A), and m is an integer from 2 to 8, wherein each X for each value of m [(which is an integer from 2 to 8), each X] is independently the same or

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G1 different [for each X_m], and

n is an integer [of] from 1 to 3.

G2 ~~4~~5. (Twice amended) The isolated peptide according to claim 1, wherein [none of the amino acids corresponding to each] R^1 [in R^1_a], [each] R^2 [in R^2_b], and [each] R^3 [in R^3_c] do not comprise an amino acid selected from the group consisting of A, B, C as defined in claim 1.

~~7~~8. (Four times amended) An isolated peptide comprising [amino acids 1 to 19 of] SEQ ID NO:1.

~~8~~9. (Four times amended) An isolated peptide comprising [amino acids 1 to 19 of] SEQ ID NO:2.

G3 ~~9~~10. (Four times amended) An isolated peptide comprising [amino acids 1 to 19 of] SEQ ID NO:3.

~~10~~11. (Four times amended) An isolated peptide comprising [amino acids 1 to 19 of] SEQ ID NO:4.

~~11~~12. (Four times amended) An isolated peptide comprising [amino acids 1 to 29 of] SEQ ID NO:5.

G4 ~~13~~15. (Thrice amended) A pharmaceutical composition comprising [an] the isolated peptide according to claim 1 as an active component for treating microbial infection and a pharmaceutically acceptable carrier in a pharmaceutically acceptable dosage form.

~~14~~16. (Amended) The pharmaceutical composition according to claim ~~15~~13, wherein the infection is caused by an organism or a compound of an organism, said organism being selected from the group [comprising] consisting of a bacterium, a fungus, a virus and a parasite.

G5 ~~20~~22. (Twice amended) The pharmaceutical composition according to claim ~~15~~13, further comprising an antibiotic selected from the group consisting of penicillins, cephalosporins, β -lactams, aminoglycosides, quinolones, tetracyclines, macrolides, glycopeptides or lipopeptides, [hydrophobic antibiotics,] ribosome inhibitors or antibiotics having a large lipid-like lactone ring.

G6 24
28. (Twice amended) A method for treatment of microbial infection in a mammal, comprising administering to a mammal in need of such treatment [a therapeutically effective] an amount of [an] the isolated peptide according to claim 1 effective to reduce infection.

30 44. (Twice amended) A method for treatment of microbial infection in a human, comprising administering to a human in need of such treatment [a therapeutically effective] an amount of [an] the isolated peptide according to claim 1 effective to reduce infection.

3 145. (Twice amended) A method for inhibiting the growth of a microbe, comprising the step of contacting a microbe with an [effective] amount of [an] the isolated peptide according to claim 1 effective to inhibit the growth of a microbe.

G7 32 46. (Twice amended) A method for inhibiting the growth of a Gram-negative bacterium, comprising the step of contacting a Gram-negative bacterium with an [effective] amount of [an] the isolated peptide according to claim 1 effective to inhibit the growth of a Gram-negative bacterium.

33 47. (Twice amended) A method for inhibiting the growth of a Gram-positive bacterium, comprising the step of contacting a Gram-positive bacterium with an [effective] amount of [an] the isolated peptide according to claim 1 effective to inhibit the growth of a Gram-positive bacterium.

34 48. (Twice amended) The isolated peptide according to claim 1, wherein R^2_b is ACAA, wherein each A and C is as independently defined in claim 1.

The Oath/Declaration filed March 24, 2003 is acknowledged.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

April 24, 2003

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